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FOLEY HOAG, LLP

PATENT GROUP, WORLD TRADE CENTER WEST

155 SEAPORT BLVD

BOSTON, MA 02110

EXAMINER

SHARMA, YASHITA

ART UNIT

PAPER NUMBER

3774

MAIL DATE

DELIVERY MODE

01/15/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/572,737

Applicant(s)

LOTFY, WAEI MOHAMED NABIL

Examiner

YASHITA SHARMA

Art Unit

3774

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 May 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,7-15,17 and 18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,7-15,17 and 18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 March 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB08)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

Status of claims

1. This office action is responsive to the preliminary amendment filed on 05/14/2007. As directed by the amendment: claims 8-14 have been amended, claims 3-6 and 16 have been cancelled, and new claims 17 and 18 have been added. Thus, claims 1, 2, 7-15, 17 and 18 are presently pending in this application.

Drawings

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "lining" in claims 1, 2, 14, 15, 17 and 18; "ribbon" in claim 11; the "ball" in claims 7-13 and the "a plug of an elastomer" in claim 10 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for

consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

3. The drawings are objected to under 37 CFR 1.83(b) because they are incomplete. 37 CFR 1.83(b) reads as follows:

When the invention consists of an improvement on an old machine the drawing must when possible exhibit, in one or more views, the improved portion itself, disconnected from the old structure, and also in another view, so much only of the old structure as will suffice to show the connection of the invention therewith.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the

examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
- (e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
- (f) BACKGROUND OF THE INVENTION.
 - (1) Field of the Invention.
 - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (g) BRIEF SUMMARY OF THE INVENTION.
- (h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (i) DETAILED DESCRIPTION OF THE INVENTION.
- (j) CLAIM OR CLAIMS (commencing on a separate sheet).
- (k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
- (l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

Content of Specification

- (a) Title of the Invention: See 37 CFR 1.72(a) and MPEP § 606. The title of the invention should be placed at the top of the first page of the specification unless the title is provided in an application data sheet. The title of the invention should be brief but technically accurate and

descriptive, preferably from two to seven words may not contain more than 500 characters.

- (b) Cross-References to Related Applications: See 37 CFR 1.78 and MPEP § 201.11.
- (c) Statement Regarding Federally Sponsored Research and Development: See MPEP § 310.
- (d) The Names Of The Parties To A Joint Research Agreement: See 37 CFR 1.71(g).
- (e) Incorporation-By-Reference Of Material Submitted On a Compact Disc: The specification is required to include an incorporation-by-reference of electronic documents that are to become part of the permanent United States Patent and Trademark Office records in the file of a patent application. See 37 CFR 1.52(e) and MPEP § 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text were permitted as electronic documents on compact discs beginning on September 8, 2000.
- (f) Background of the Invention: See MPEP § 608.01(c). The specification should set forth the Background of the Invention in two parts:
 - (1) Field of the Invention: A statement of the field of art to which the invention pertains. This statement may include a paraphrasing of the applicable U.S. patent classification definitions of the subject matter of the claimed invention. This item may also be titled "Technical Field."
 - (2) Description of the Related Art including information disclosed under 37 CFR 1.97 and 37 CFR 1.98: A description of the related art known to the applicant and including, if applicable, references to specific related art and problems involved in the prior art which are solved by the applicant's invention. This item may also be titled "Background Art."
- (g) Brief Summary of the Invention: See MPEP § 608.01(d). A brief summary or general statement of the invention as set forth in 37 CFR 1.73. The summary is separate and distinct from the abstract and is directed toward the invention rather than the disclosure as a whole. The summary may point out the advantages of the invention or how it solves problems previously existent in the prior art (and preferably indicated in the Background of the Invention). In chemical cases it should point out in

general terms the utility of the invention. If possible, the nature and gist of the invention or the inventive concept should be set forth. Objects of the invention should be treated briefly and only to the extent that they contribute to an understanding of the invention.

- (h) Brief Description of the Several Views of the Drawing(s): See MPEP § 608.01(f). A reference to and brief description of the drawing(s) as set forth in 37 CFR 1.74.
- (i) Detailed Description of the Invention: See MPEP § 608.01(g). A description of the preferred embodiment(s) of the invention as required in 37 CFR 1.71. The description should be as short and specific as is necessary to describe the invention adequately and accurately. Where elements or groups of elements, compounds, and processes, which are conventional and generally widely known in the field of the invention described and their exact nature or type is not necessary for an understanding and use of the invention by a person skilled in the art, they should not be described in detail. However, where particularly complicated subject matter is involved or where the elements, compounds, or processes may not be commonly or widely known in the field, the specification should refer to another patent or readily available publication which adequately describes the subject matter.
- (j) Claim or Claims: See 37 CFR 1.75 and MPEP § 608.01(m). The claim or claims must commence on separate sheet or electronic page (37 CFR 1.52(b)(3)). Where a claim sets forth a plurality of elements or steps, each element or step of the claim should be separated by a line indentation. There may be plural indentations to further segregate subcombinations or related steps. See 37 CFR 1.75 and MPEP § 608.01(i)-(p).
- (k) Abstract of the Disclosure: See MPEP § 608.01(f). A brief narrative of the disclosure as a whole in a single paragraph of 150 words or less commencing on a separate sheet following the claims. In an international application which has entered the national stage (37 CFR 1.491(b)), the applicant need not submit an abstract commencing on a separate sheet if an abstract was published with the international application under PCT Article 21. The abstract that appears on the cover page of the pamphlet published by the International Bureau (IB) of the World Intellectual Property Organization (WIPO) is the abstract that will be used by the USPTO. See MPEP § 1893.03(e).
- (l) Sequence Listing. See 37 CFR 1.821-1.825 and MPEP §§ 2421-2431. The requirement for a sequence listing applies to all sequences disclosed in a given application, whether the sequences are claimed or not. See MPEP § 2421.02.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1, 2, 7-15, 17 and 18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification fails to describe the invention clearly and list specific details of the function the device performs and the structure of the device.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1, 2 and 7 -10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
8. Regarding claims 1 and 2, the preambles as worded is confusing. It is unclear what applicant is attempting to claim. Are the claims directed to a lining, the subcombination of a lining and a stent or other subcombination thereto. It is unclear as to what is meant by "the lining to stents to function as a valve" in claim 1 and "fixed lining narrowing excluding animal native or treated valves to stents" in claim 2.

9. Regarding claim 7, the preamble is directed to a ball. There is no apparent nexus between the ball and the stent/lining of the preceding claims. It is not clear if applicant is attempting to claim only the ball or some subcombination thereof.
10. Claims 8 and 9, applicant has failed to establish any nexus between the ball and any other structures or elements of the valve. Therefor it is unclear how the check valve relates to the ball in claims 8 and 9
11. Regarding claim 10, there is no antecedent support for "the tubing". It is unclear how the ball is related to the valve and how the plug is related to either the ball or the valve.
12. Claims 1, 2, 7-15, 17 and 18 are rejected as failing to define the invention in the manner required by 35 U.S.C. 112, second paragraph.

The claim(s) are narrative in form and replete with indefinite and functional or operational language. The structure which goes to make up the device must be clearly and positively specified. The structure must be organized and correlated in such a manner as to present a complete operative device. The claim(s) must be in one sentence form only. Note the format of the claims in the patent(s) cited.

The claim(s) are narrative in form and replete with indefinite and functional or operational language. The structure which goes to make up the device must be clearly and positively specified. The structure must be organized and correlated in such a manner as to present a complete operative device. The claim(s) must be in one sentence form only. Note the format of the claims in the patent(s) cited.

Claim Rejections - 35 USC § 102

Note to applicant: the rejections that follow are made in as much the examiner can best understand the claims in light of applicant's specification. The specification is minimally comprehensible as to allow for a limited but reasonable search of the prior art by the examiner. Examiner is interpreting independent claims 1 and 2 as being directed to a combination of a lining and a stent. For claim 7, the claim is interpreted as being directed to a ball valve in combination with a lining/stent device.

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. **Claims 1, 2, 7, 12, 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Pavcnik et al. (5,397,351).**

15. Regarding claims 1 and 2, as best understood, Pavcnik discloses a fixed Dacron lining (ring, 14) (Fig. 1), tubular stent 20 (Fig. 1) where the lining functions as a valve 10 (Fig. 1) for the flow of fluids or gases through.

16. Regarding claim 7, as best understood, Pavcnik discloses a ball (balloon 18) (Fig. 1) for the valve mechanism, inflated with flowable gelatinous material (col. 6, lin. 32-34).

17. Regarding claims 12 and 13, Pavcnik discloses the ball (balloon 18) (Fig. 1) is separate from the stent 20 (Fig. 1) and is modifiable and retrievable after implantation to allow further sizing as needed (the ball is inflatable and can be retrieved after implantation to modify the amount of inflation, col. 4, lin. 32-44).

Claim Rejections - 35 USC § 103

18. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

19. **Claims 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pavcnik et al. (5,397,351) in view of Block et al. (5,554,185).**

20. Regarding claims 8 and 9, Pavcnik discloses the claimed invention; except for a check valve for inflation or deflation of a breakaway design to permit separation from the means for injecting. However, Block teaches a similar device comprising a check valve with a tube 20 (Fig. 1a) that can be removed to permit separation from the means for injecting (col. 4, lin. 1-9). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention was made to modify the device in Pavcnik to include a check valve for inflation or deflation of a breakaway design to permit separation from the

means for injecting, for the purpose of preventing leakage or seepage of the inflation material (col. 4, lin. 7-9).

21. Regarding claim 10, as best understood, Pavcnik discloses the claimed invention except for a one way valve comprises a plug having a slit through which closes upon application of pressure within the tubing. However, Block teaches a similar device comprising a check valve with a tube 20 (Fig. 1a) that has a slit to allow the flow of inflatable material which closes upon application of pressure within in the tube. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention was made to modify the device in Pavcnik to include a one way valve comprising a plug having a slit through which closes upon application of pressure within the tubing., for the purpose of allowing flow of the inflation material in one direction and preventing leakage or seepage of the inflation material in the backward direction (col. 4, lin. 7-9).

22. **Claims 14, 15, 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pavcnik et al. (5,397,351) in view of Chinn et al. (7,081,133 B2) further in view of Samson (5,370,691).** Pavcnik discloses the claimed invention; except for the lining is fabricated solely or at least partly from a semi permeable membrane, and wherein the hollow wall has disposed hydrophilic gel capable of absorbing a liquid to thereby increase the volume of the gel, wherein the final shape of the lining may be appropriate or modifiable by ballooning from the lumen or by inflation. However, Chinn teaches a similar device comprising a lining (cuff, 12) (Fig. 1) fabricated from a semi permeable membrane capable of absorbing a liquid disposed with

antimicrobial substance (col. 8, lin. 60-64). Furthermore, Samson teaches an inflatable stent 200 (Fig. 1) with a hollow wall having a modifiable shape filled with a gel (col. 5, lin. 26-28) capable of absorbing a liquid.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention was made to modify the device in Pavcnik to include a lining fabricated solely or at least partly from a semi permeable membrane, and wherein the hollow wall has disposed hydrophilic gel capable of absorbing a liquid to thereby increase the volume of the gel, wherein the final shape of the lining may be appropriate or modifiable by ballooning from the lumen or by inflation, for the purpose of allowing expansion of the device to contact the surrounding walls of the implantation site which would enhance blood flow through the device and prevent any blood from flowing back in the opposite between the external surface of the device and the surrounding tissue walls.

25. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pavcnik et al. (5,397,351) in view of Tai et al. (6,709,604 B2). Pavcnik discloses the claimed invention including a stent 20 (Fig. 1) and ball (balloon 18) (Fig. 1) made of biocompatible materials; except for the ball is linked to the stent by a ribbon of biologically inert material to allow limited mobility of the ball. However, Tai teaches a similar device comprising a cap attached to a check valve 10 (Fig. 1) by ribbons (twist up tethers 25) (Fig. 1). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention was made to modify the device in Pavcnik to include a ribbon of biologically inert material to allow limited mobility of the ball, for the purpose of

preventing the ball from getting trapped with the internal walls of the device by providing resistance to the vertical displacement in response to fluid flow (col. 3, lin. 4-7).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to YASHITA SHARMA whose telephone number is (571)270-5417. The examiner can normally be reached on Monday - Thursday, 8 am to 4 pm EST..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on 571-272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Y. S./

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Examiner, Art Unit 3774

/David J. Isabella/

Supervisory Patent Examiner, Art Unit 3774